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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	: Michael Simons & Youhe Gao
Serial No.	: 09/426,011
Filed	: October 25, 1999
For	: "METHOD FOR PR-39 PEPTIDE REGULATED STIMULATION OF ANGIOGENESIS"
Examiners	: Roy Teller & Brenda Brumback
Group Art Unit	: 1654
Attorney's Docket No.	: BIS-043/CIP

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Attorney for applicants: David Prashker

Signature: [signature]

Date: April 15, 2003

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RESPONSE TO RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
Box Non-Fee Amendment
Washington, D.C. 20231

Dear Sir:

In response to the non-final Office Action mailed April 7th, 2003 for the above-identified application in which a Restriction Requirement pursuant to 35 U.S.C. 121 has been made, applicants now formally take the following actions and positions.

(i). Applicants formally traverse the Restriction Requirement as presented by the Examiners for the reasons stated below; and

(ii). Applicants provisionally elect to prosecute claims 11-14 respectively, identified as Group III, and drawn to a family of PR-39 derived oligopeptides.

In addition, since there is no present demand that an election of species be made, applicants make no such choices or selections as a matter of formal record. Accordingly, no choices or selections as such among the different sequence identification numbers, cell types, tissue types, or means of introduction are made herein. Nevertheless, if the Examiners must have particulars upon which to base any future evaluation and review, logic dictates that an exemplary oligopeptide member embodying the PR-39 oligopeptide collective, such as that defined by claim 12 and represented by SEQ ID NO:3, might be of useful service.

REMARKS

1. Applicants respectfully submit that the Examiners' demand for a Restriction Requirement under 35 U.S.C. 121 at this time is procedurally inappropriate and manifestly unfair. The present invention, as originally defined by claims 1- 14 respectively, has been

of record since October 25, 1999; has been substantively prosecuted as shown by multiple Official Actions and Responses; and has been shuffled from one Patent Examiner to another for three and one half years.

Applicants contend also that the present Examiners of record cannot treat the instant application as pending claims 1-14 were totally new or previously unexamined claims; nor can the present Examiners pretend that the pending claims were not previously reviewed on the merits as a whole, collectively and cumulatively.

Applicants maintain, therefore, that the present Examiners must accept and be bound by the entirety of the prosecution history to date for what it actually is; and also come to recognize that their demand for Restriction of the claims is legally inequitable as well as procedurally improper.

2. Applicants respectfully submit and maintain that all of claims 1-14 respectively constitute a single and unitary invention; and define an integrated subject matter having multiple formats presented in both broader and narrower recitations. Thus, a single subject matter as a whole comprising applicants' integrated invention is defined in the alternative by independent claims 1, 2 and 11 respectively. Moreover, applicants' subject matter as a whole is defined in the alternative by

claims 1-10 as a broad methodology and by claims 11-14 as a composition of matter comprising a family of pharmacologically active oligopeptides.

The Examiners will note and appreciate that amended independent claim 1 is directed to a method for stimulating angiogenesis within a targeted collection of viable cells; whereas amended independent claim 2 defines the same invention as a method for altering proteosome-mediated degradation of peptides within a collection of viable cells. Equally important, amended method claims 1 and 2 are very similar in language as well as in the requirements and limitations expressly recited by the manipulative steps. Each method identifies a collection of cells as the target; each provides means for introducing at least one member of the PR-39 oligopeptide collective to the cytoplasm of the targeted cells; and each explicitly requires the introduced member of the PR-30 oligopeptide collective to interact with such proteosomes as are present within the cytoplasm of the targeted cells in three specified ways. Thus, the method defined alternatively by amended independent claims 1 and 2 respectively are intimately and directly related to each other.

Similarly, composition claims 11-14 respectively are alternative recitations for the family constituting the PR-39 oligopeptide collective, whose members individually are able to cause an inhibition of

proteosome-mediated degradation for at least one peptide in-situ after being introduced to the cytoplasm of a viable cell. Amended independent claim 11 recites five explicit requirements for each member constituting this family of derived oligopeptides; and each preferred member defined by claims 12-14 respectively is able to alter the proteolytic activity of the proteosomes such that a marked increased expression of an identifiable peptide occurs as a consequence.

All of pending claims 1-14 thus constitute a single invention defined in the alternative; and provides both broader and narrower recitations of operative methods as well as a delineated family of PR-39 derived oligopeptides directed to only one goal and objective - an inhibition of proteosome-mediated degradation. It will noted also that each method defined by claims 1 and 2 requires the introduction of a PR-39 oligopeptide collective member, which are delineated by claims 11-14 respectively; and that the method of claims 1 and 2 require that the consequence of PR-39 oligopeptide collective interaction be a marked inhibition of proteosome-mediated proteolytic degradation acitivity.

Clearly therefore, all of the presently pending claims 1-14 are intimately related to each other; all commonly share the same essential features and requisite manipulative steps; and all share a

single inventive concept and basis, regardless of the scope and detail recited within each of the independent claims. Accordingly, independent claims 1-14 thus constitute a single, unitary invention.

3. The Examiners unfortunately appear to have been mislead and distracted by the wording and varying scope of protection presented by amended independent claims 1, 2 and 11; and have not recognized nor acknowledged the overlapping subject matter or commonality shared manipulative steps recited by each of method claims 1, 2 respectively with respect to claim 11. Applicants respectfully submit and maintain that methods claims 1 and 2 do not have different objectives from composition claim 11; do not perform meaningfully different functions; and do not utilize meaningfully different properties to achieve different effects or results. To the contrary, method claims 1 and 2 recite two aspects of a single, broadly recited process, the results and consequences of which proceed sequentially and are defined in parallel; yet all of which originate from a common set of specified properties and reaction characteristics provided by a member of the PR-39 oligopeptide collective.

The Examiners have also failed to provide any acceptable reasoning or rational basis for their stated view that the methods defined by claim 1 and 2 are unrelated to the PR-39 oligopeptide

collective defined by claim 11. The Examiners have merely looked superficially at the preamble of claims 1 and 2 while denying and ignoring the substantive identity of the manipulative steps recited within the body of each independent claim. Applicants respectfully submit that this view and position is factually unfounded; is subjectively speculative; and is legally erroneous.

Contrary to the Examiners' stated view, there is only one broad invention which employs similar manipulations and derived PR-39 oligopeptide compositions in common to achieve similar results and consequences. Note that the same altered proteolytic degradation of the interacting proteosome is required by both claims 1 and 2 individually; and this common result is the outcome of one single technique and series of manipulations using the PR-39 oligopeptide collective members as workpieces as alternative definitions of the same invention.

In sum, Applicants therefore respectfully submit and maintain that the Examiners have unfortunately misapplied the legal standards and misconstrued the underlying facts needed for now imposing a Restriction Requirement for presently pending claims 1-14. Applicants also respectfully affirm that all of pending claims 1-14 are intimately and directly related in sum and substance; and that each of

independent claims 1, 2 and 11 recites similar requirements which differ only incidentally in the scope of the definition and not in the substantive essentials. Thus, all the presently pending claims constitute a single, yet broad invention which has been defined in the alternative to preserve the true value of applicants' invention. Applicants again submit that there is no compelling reason for now demanding a Restriction of presently pending claims 1-14 in that all these claims are alternative definitions of one, unified invention.

For all the reasons stated herein, applicant respectfully requests that the Examiners reconsider their position and withdraw the presently imposed Restriction Requirement completely and in its entirety. The Examiners are also invited to call applicants' undersigned attorney should they feel that such a telephone call would further the prosecution of the present application.

Respectfully submitted,

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Date: April 15, 2003

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